REMARKS

This communication is responsive to the Office Action dated **December 16, 2010**. The claims have not been amended by way of this communication. Claims 25-40 remain pending.

In an interview with the Examiner on January 11, 2011, Applicant's representative, namely James Shands (Reg. No. 54,439), clarified a typographical error in the Office Action dated December 16, 2010. In particular, the Examiner indicated that the Office rejected claims 25-35 and 37-40 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,123,697 to Shippert et al. ("Shippert") as modified by U.S. Patent No. 5,395,309 to Tanaka ("Tanaka").

Claim Rejection—35 U.S.C. § 102

The Office rejection claims 25, 28-31, 34, and 37-39 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0171563 to Heinrich et al. ("Heinrich"). Applicant respectfully traverses the rejection.

Heinrich fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no apparent reason for modification to include such features. For example, Heinrich fails to disclose or suggest all the features of claim 25. Heinrich fails to disclose a medical device for delivering a therapeutic agent to an internal portion of a patient's body that comprises, among other things, a ***self-expanding*** delivery member in operative communication with the shaft, the delivery member having a proximal end and a distal end and being shaped in a continuous solid cylindrical configuration from a porous material capable of (i) releasing the therapeutic agent to the internal portion of the patient's body and (ii) being in a collapsed state, as recited in claim 25. As indicated in Applicant's disclosure,[1] "retention member 34 may be operated to release agent delivery member 18 from its collapsed condition, causing agent delivery member 18 to ***self-expand*** to a pre-determined diameter and bringing agent delivery member 18 into intimate contact with a target vessel wall 46" (emphasis added.) In other words, deliver member 18 is biased such that it expands due to the removal of retention member 34, rather than by the addition of fluid or liquid, for example.

This is in contrast to the disclosure of Heinrich. Anchor 114 of Heinrich is ***not*** self-

[1] Applicant's specification, paragraph [0020].

expanding, as in claim 25. Rather, Heinrich states,[2] "[i]n use, anchor 114 expands from the initial condition to the expanded condition upon addition of moisture, fluid or liquid (e.g., water, saline, sterile water and the like) thereto." In no manner does Heinrich disclose or suggest that anchor 114 may be ***self-expanding***, as in claim 25.

Furthermore, it is improper for the fluid or liquid, e.g., water, saline, sterile water and the like, used to expand anchor 114 in Heinrich to also be considered a therapeutic agent for delivery to an internal portion of a patient's body, as implied by the Office. Claim 25 expressly recites a device for delivering a therapeutic agent to an internal portion of a patient's body that comprises a self-expanding delivery member. By expressly indicating that anchor 114 is self-expanding (via the fluid or liquid) and by implying that the fluid or liquid used to expand anchor 114 is also a therapeutic agent, it appears that the Office has considered the fluid or liquid in Heinrich to be both for expansion ***and*** a therapeutic agent. However, the separate recitation in claims 25 of a self-expanding delivery member and a therapeutic agent makes clear that the therapeutic agent does not expand the self-expanding delivery member. As such, it is improper for the fluid or liquid used to expand anchor 114 in Heinrich to also be considered a therapeutic agent for delivery to an internal portion of a patient's body.

Finally, Heinrich fails to disclose a porous material ***capable of releasing a therapeutic agent*** to an internal portion of a patient's body, as recited in claim 25. In no manner does Heinrich disclose or suggest releasing a therapeutic agent to an internal portion of a patient's body, much less releasing a therapeutic agent to an internal portion of a patient's body via anchor 114. Rather, Heinrich is directed toward an anastomosis device in which anchor 114 in an expanded condition inhibits withdrawal of sleeve 102 from bladder "B", thereby allowing bladder "B" to be moved toward urethra "U", for example.[3] No portion of Heinrich discloses that anchor 114 is capable of releasing a therapeutic agent to an internal portion of a patient's body, as in claim 25.

For at least the reasons presented above, Heinrich fails to disclose or suggest all the elements of independent claim 25. Applicant requests that the rejection be withdrawn and that claim 25 be allowed.

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[2] Heinrich at paragraph [0059].
[3] Heinrich, paragraphs [0006] and [0071], and FIGS. 7 and 9.

Claims 28-31, 34, and 37-39 depend from independent claim 25. At least by virtue of their dependency, claims 28-31, 34, and 37-39 are also patentable over Heinrich.

Claim Rejections—35 U.S.C. § 103

The Office rejected claims 25-35 and 37-40 under 35 U.S.C. § 103(a) as being unpatentable over Shippert as modified by Tanaka. The Office also rejected claims 26, 27, and 40 under 35 U.S.C. § 103(a) as being unpatentable over Heinrich as modified by Shippert. The Office also rejected claim 36 under 35 U.S.C. § 103(a) as being unpatentable over Heinrich.

Applicant respectfully traverses these rejections. Even if considered in combination, the applied references fail to disclose or suggest each and every feature of Applicant's claims, and would have provided no apparent reason for modification to include such features.

Claims 25-35 and 37-40

Even if considered in combination, the applied references fail to disclose all the features of claim 25. Shippert fails to disclose a medical device for delivering a therapeutic agent to an internal portion of a patient's body that comprises, among other things, a ***self-expanding*** delivery member in operative communication with a shaft, as recited in claim 25. That is, device 100 in FIG. 11 of Shippert is ***not*** a ***self-expanding*** delivery member. Instead, Shippert states the following:

> The packing member 24 is made of a material that absorbs fluids, including body fluids, such as blood. In certain embodiments, the packing member 24 is made from a polyvinyl alcohol (PVA) or polyurethane foam or sponge, or other foam materials, which is formed or manufactured into desired sizes for placement in a particular body cavity. As illustrated in FIG. 1, the packing member 24 is initially in a compressed or unexpanded state. ***When the packing member 24 absorbs fluids, it is able to expand to a desired size.*** In one embodiment, the thickness along most of the length of the packing member 24, when placed in a body cavity, expands upon receiving fluid to about 1.5-7 times its compressed or unexpanded state. As can be understood, the portions of the packing member that expand are dependent upon their location in the body cavity. ***Little or no expansion occurs of those portions of***

> ***the packing member 24 that contact a wall of the body cavity***.[4] (Emphasis added.)

In no manner does the above-quoted portion, nor any other portion of Shippert, disclose or suggest that device 100 may be ***self-expanding***, as in claim 25. Rather, as seen from the portion of Shippert quoted above, the device in Shippert expands when it absorbs fluids. As such, the device in Shippert is not ***self-expanding***.

As acknowledged by the Office,[5] Shippert does not disclose "a retention member in operative communication with the delivery member, the retention member being configured and arranged to selectively collapse the delivery member." In order to support the rejection of claim 25, the Office asserted that Tanaka discloses such a feature. In particular, the Office stated the following:[6]

> It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Shippert with the teaching of Tanaka el al, since such a modification would simplify the insertion of the device of Shippert into the nasal cavity, by preventing the device from expanding (via the sheath member) until it has been properly positioned within the nasal cavity (see column 1, lines 5-20).

Applicant respectfully submits that this reason for modification is not convincing. As indicated above, Shippert does not disclose a ***self-expanding*** delivery member, as recited in claim 25. Indeed, as stated in Shippert, "***little or no expansion occurs of those portions of the packing member 24 that contact a wall of the body cavity***."[7] As such, there would have been no apparent reason to provide a retention member "to prevent[] the device from expanding until it has been properly positioned within the nasal cavity,"[8] as asserted by the Office.

For at least these reasons, the Office has failed to establish a prima facie case for non-patentability of Applicant's claim 25 under 35 U.S.C. § 103(a). Claims 26-35 and 37-40 depend from claim 25 and, at least by virtue of their dependency, are also non-obvious over the applied

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[4] Shippert, col. 5, lines 7-25.
[5] Office Action, dated December 16, 2010, page 3.
[6] *Id.* at page 3-4.
[7] Shippert, col. 5, lines 23-25.
[8] Office Action, dated December 16, 2010, pages 3-4.

references. Withdrawal of this rejection is requested.

Claims 26, 27, and 40

As indicated above, Heinrich fails to disclose or suggest all the features of independent claim 25 from which claims 26, 27, and 40 depend. As such, the addition of any disclosure in Shippert with respect to the particular features of claims 26, 27, and 40 doe nothing to remedy the deficiencies of Heinrich. Thus, claims 26, 27, and 40 are non-obvious over the purported combination of Heinrich and Shippert. For at least these reasons, the Office has failed to establish a prima facie case for non-patentability of Applicant's claims 26, 27, and 40 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claim 36

As indicated above, Heinrich fails to disclose or suggest all the features of independent claim 25 from which claim 36 depends. Regardless of what the Office alleged to be a matter of design choice, or what a person of ordinary skill allegedly would have known, with respect to the elements of claim 36, Heinrich still fails to disclose or suggest all the features of independent claim 25.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Respectfully submitted,

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